

REMARKS

Claims 1-19 are pending. Claims 1, 2, 11 and 12 are amended. Claims 9 and 10 are cancelled. Claims 17-19 are withdrawn, pursuant to an Election of Species Requirement mailed September 30, 2005 and Response thereto filed October 31, 2005, although the rejoinder thereof is respectfully requested. No new matter is submitted. Accordingly, entry and consideration of the Amendment filed herewith is respectfully requested.

Applicants reiterate the traversal of the Election of Species Requirement for the reasons noted in the Response thereto filed October 31, 2005, notwithstanding the commentary set forth in the current Office Action with respect to the Response. Applicants further reiterate the assertion of claim 11 as generic to all Species, as each Species includes at least the features recited therein, particularly where either or both of the jaws of the elected species of Figures 7A and 7B are identified as alterable to comprise an ultrasonic vibratory element, i.e., transducer, as in paragraph [0044], for example, which transducer is understood as that transducer earlier described with reference to Figures 1-3, for example, in the Specification. Accordingly, rejoinder of claims 17-19 is respectfully requested.

With respect to the Drawings objections raised in the Office Action, claims 9 and 10 have been cancelled, thereby obviating any drawing objection based on a recitation of a third or fourth passage. The basis for all other Drawings objections are refuted herein as the first and second passages are shown in at least Figures 2 and 8, a reflector (window 16, 216-716) is shown in at least Figures 2 and 4A-4F, and an ultrasonic transducer element in combination with a compliant member with electrodes is shown in at least Figures 7A, 7B and 8, wherein a skilled artisan would readily understand based on the written description that such first and second passages, reflector (window), and compliant member with electrodes is intended in all embodiments. Accordingly, all of the Drawing objections having been obviated and addressed,

withdrawal of said Drawing objections is respectfully requested. Applicants will submit formal drawings in due course after notification of withdrawal of the Drawing objections is received.

In the Office Action, claims 11-16 are rejected under 35 U.S.C. 112, 1st paragraph as allegedly not enabled for failing to show how various energy sources, i.e., ultrasound, microwave, cryoablation, RF, etc., would be used with the electrodes shown in Figures 7A and 7B. Applicants traverse the rejection on this basis however as paragraphs [0043] and [0044] amply describe that the electrodes are “operatively connected to an energy source, for example, ultrasound, microwave, cryoablation, radio-frequency (RF), photodynamic, laser, or cautery.”. Moreover, paragraph [0043] further describes that the electrodes through which the energy is provided are “...on the surface of the compliant material...” or “Alternatively or additionally, ... intergrated into the surface of the compliant material.” Moreover, a carbon fiber or other conductive material is described for providing the selected energy through electrodes “...woven into a bounding surface of compliant material ...”. Applicants assert that such description more than adequately provides support for the various energies and the configuration of the electrodes relative to the compliant material for providing such energies, as recited in the claims. Accordingly, withdrawal of the 35 U.S.C. 112, 1st paragraph rejection of claim 11-16 on this basis is respectfully requested.

With respect to the 35 U.S.C. 112, 1st paragraph rejection of claims 11-16 based on the alleged failure to describe how an ultrasound transducer is attached to a compliant material or for allegedly failing to show a transducer head with a compliant material, Applicants assert that paragraph [0044] states that “Alternatively or additionally, an ultrasonic vibratory element may be provided in one or both of jaws 1002a, 1002b.”. Thus, when taken with the description of the earlier described ultrasonic transducer in the Specification, with respect to Figures 1-3, and the clamping mechanism comprised of a compliant material usable with the

various embodiments of the claimed invention, as described in the Specification at paragraphs [0040] – [0042], for example, a skilled artisan would readily understand that the applicator recited in claims 11-16 is properly construed as alternatively or additionally comprising such an ultrasonic transducer along with the compliant material. Moreover, as discussed above, the compliant material is readily described as incorporating electrodes in or on the surface of the compliant material. Thus, the 35 U.S.C. 112, 1st paragraph issue having been addressed herein, withdrawal of the 35 U.S.C. 112, 1st paragraph rejection of claims 11-16 on the basis of allegedly not describing an ultrasonic transducer in combination with a compliant material is respectfully requested.

With respect to the 35 U.S.C. 112, 2nd paragraph rejection of claims 2-6, 10, and 12-16, claims 2 and 12 have each been amended to obviate the alleged indefiniteness and to provide appropriate antecedent basis in each case. Accordingly, withdrawal of the 35 U.S.C. 112, 2nd paragraph rejection of claims 2-6, 10, and 12-16 is respectfully requested.

In the Office Action, claims 1, 2, 4-6 and 11-14 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by U.S. Patent Publication No. 2002/0042610 to Sliwa, Jr. et al. (hereafter “Sliwa”). The rejection is respectfully traversed.

To maintain a 35 U.S.C. 102(b) rejection, a reference must teach each and every element of a claimed invention. Sliwa does not do so.

Applicants’ independent claim 1 recites an applicator for creating a lesion in tissue comprising, *inter alia*, a first rigid or semi-rigid support member, a first compliant material coupled to the first support member, a first passage in communication with the first compliant material for infusing a medium to the compliant material, and at least one electrode for conducting energy to an outer surface of the tissue. Applicants’ independent claim 11 recites an applicator for creating lesions in tissue comprising, *inter alia*, a first rigid or semi-rigid support

member, an ultrasonic transducer element mounted to the first support member, and means for varying the distance between the ultrasonic transducer element and an outer surface of the tissue.

Sliwa is relied on in the Office Action as allegedly disclosing at least the features of Applicants' claims 1 and 11 recited above. Sliwa, however, discloses an ablation device 400 (Figure 67) comprised of a number of adjacent cells 402 each having an ultrasonic transducer element 406 housed within a housing 410 comprised of an enclosure 412 and a top 414. The housing 410 is then mounted into an opening 446 in a suction body 448 that is further provided with suction recesses 454 (Figure 64) for adhering the device 400 to tissue (paragraph [0209]). A distributing element 420 is attached to the transducer 406 (paragraph [0207]), and a compliant membrane 460 is adhered to a bottom of the enclosure 412 (paragraph [0211]). That which the Office Action relies on as a first support member is instead one of the adjacent cells 402 in Sliwa. Sliwa thus fails to teach or disclose the first rigid or semi-rigid support member as recited in each of Applicants' independent claims 1 and 11. Sliwa further fails to teach or disclose the at least one electrode as recited in Applicants' independent claim 1. Further still, Applicants' independent claims 1 and 11 omit the vacuum ports for adhering a device to tissue as is required in the disclosure of Sliwa relied in the Office Action. Thus, Sliwa fails to teach or disclose the combination of features recited in at least Applicants' independent claims, from which all other claims directly or indirectly depend. Moreover, the cancellation of claims 9 and 10 render any rejection thereof moot. Accordingly, withdrawal of the 35 U.S.C. 102(b) rejection of claims 1, 2, 4-6 and 11-14 based on Sliwa is respectfully requested.

In the Office Action, claims 1-3 and 6-16 are rejected under 35 U.S.C. 102(e) as allegedly anticipated by U.S. Patent No. 6,547,788 to Maguire, et al. (hereafter "Maguire"). The rejection is respectfully traversed.

To maintain a 35 U.S.C. 102 rejection, a reference must teach each and every element of a claimed invention. Maguire does not do so.

Applicants' independent claim 1 recites an applicator for creating a lesion in tissue comprising, *inter alia*, a first rigid or semi-rigid support member, a first compliant material coupled to the first support member, a first passage in communication with the first compliant material for infusing a medium to the compliant material, and at least one electrode for conducting energy to an outer surface of the tissue. Applicants' independent claim 11 recites an applicator for creating lesions in tissue comprising, *inter alia*, a first rigid or semi-rigid support member, an ultrasonic transducer element mounted to the first support member, and means for varying the distance between the ultrasonic transducer element and an outer surface of the tissue.

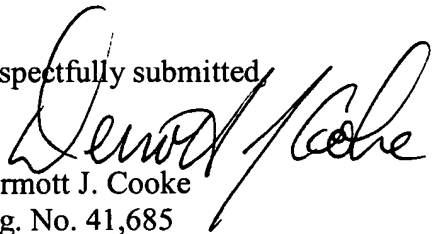
Maguire discloses a tissue ablation catheter assembly 100 that is inserted *into* an organ, tissue or vessel, such as an atrium (col. 19, lines 14-31 and col. 22, lines 1-10) in order to form lesions along a substantially circumferential region thereof. The ablation assembly 100 is comprised of a delivery member 102, an ablation member 128 comprised of an expandable member 108 and an ablation element 120 therein, and an ablation control system 118. An electrical connector 112 connects the ablation control system 118 to the ablation member 128 and ablation element 120. Once the catheter assembly 100 is located in the desired organ, tissue or vessel, then fluid, introduced to the expandable member 108 through tube 113, inflates the expandable member 108, and the ablation element 120 is activated to ablate the targeted tissue and form the desired lesion within the organ, tissue or vessel (col. 22, lines 1-22). The catheter based ablation assembly 100 of Maguire is thus substantially different than the applicator for creating lesions on an outer surface of tissue recited in Applicants' independent claims 1 and 11, from which all remaining claims directly or indirectly depend. Accordingly, because Maguire fails to teach or disclose the combination of features recited in Applicants' independent claims 1

and 11, withdrawal of the 35 U.S.C. 102(e) rejection of claims 1-3 and 6-16 based on Maguire is respectfully requested. Moreover, the cancellation of claims 9 and 10 renders any rejection thereof moot.

Applicants assert therefore, in view of the remarks made herein, that the pending claims are patentable. Accordingly, prompt reconsideration of the application is respectfully requested, and allowance of all pending claims is respectfully solicited.

Should the Examiner determine that anything further is desirable to place this application in even better form for allowance, the Examiner is invited to contact the undersigned at the telephone number indicated below.

Respectfully submitted


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